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| KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005 | | | EXAMINER PREBILIC, PAUL B | |
| | | | ART UNIT 3774 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/792,214

Applicant(s)

ZHONG, SHENG-PING

Examiner

Paul B. Prebilic

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,36,37 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,36,37 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Election/Restrictions

Claims 22-25 and 40 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the communication filed February 6, 2006. **These claims were cancelled by the amendment filed March 26, 2007.**

Terminal Disclaimer

The terminal disclaimers filed on March 26, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,197,051 and 6,723,121 have been reviewed and accepted. The terminal disclaimers have been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 is claiming two states of the product; one state where the coating has not been reacted with the bioactive agent and another where it has not. In particular, base claim 26 is in an unreacted state and the bioactive agent is not positively required. However, claim 43 appears to positively claim the bioactive agent. For this reason, it is not clear what is positively claimed. Therefore, the Examiner will treat claim 43 as if it is not positively claiming the bioactive agent.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 36, 37, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Shults et al (US 4,994,167) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shults et al (US 4,994,167) in view of Nishimura et al (US 4,888,285) or Compere et al (US 4,287,305) or Guire (US 4,979,959). Shults anticipates the claim language where BAYBOND 123 (see column 13, lines 11-46 of Shults) is equivalent to Applicant's Bayhydrol 123 (see page 8, lines 1-3 of the specification) and wherein the organic acid functional groups are the carboxylate groups on the polymer backbone; see column 13, lines 11-27. On column 13, lines 52-55, Shults states that a crosslinking agent is added to the polymer to make the polymer. It appears that the claims do not preclude the n-methyl-2-pyrrolidone contained in each of these dispersions; see columns 13 and 14 of Shults. The coating composition contains an excess of polyfunctional crosslinking agent as claimed because an excess of cross-

linking agent is not required just enough to crosslink some of the functional groups and provide functional groups capable of reacting with a bioactive agent. The bioactive agent is not positively required.

Alternatively, one could reasonably interpret the claims are requiring a molar excess with respect to all organic acid functional groups. However, the prior art, as exemplified by Nishimura (see column 6, line 4 et seq.) or Compere (see the column 3, lines 1-18 and the abstract) or Guire (see column 12, line 43 et seq. or column 13, line 32 seq.), knew to use a molar excess of crosslinking agent or reactant in order ensure that the reaction went to as close to 100% completion as possible. Therefore, it is the Examiner's position that it would have been obvious to utilize an excess of crosslinking agent with respect to all organic acid functional groups of Shults in order to ensure that the reaction goes to as close to 100% completion as possible or for the reasons that Nishimura, Compere, or Guire utilize the same.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as obvious over Shults et al (US 4,994,167) in view of Nishimura et al (US 4,888,285). Shults meets or renders obvious the claim language as explained supra but fails to disclose the type of polyfunctional crosslinking agents or the molar excess as claimed. However, Nishimura teaches that it was known to use the three or more functional group crosslinking agents in molar excess was known; see the previously cited portions thereof. Therefore, it is the Examiner's position that it would have been obvious to utilize the same crosslinking agents in excess as taught by Nishimura in the Shults invention for the same reasons that Nishimura utilizes the same.

Response to Arguments

Applicant's arguments filed August 13, 2007 have been fully considered but they are not persuasive.

In response to the traversal of the Shults anticipation rejection that Shults has no excess of crosslinking agent, the Examiner asserts that the claim language is fully met because the claim language pertaining to the excess relative to the organic acid functional groups is not clear. Therefore, it reads on any unreacted crosslinking agent in the unreacted aqueous dispersion as long as one or possibly two of the groups are reacted. Alternatively, it would have been at least obvious to utilize excess crosslinking agent to ensure the reaction goes as close to 100% completion as possible.

The Applicant also argues that there is an insufficient amount of crosslinking agent to crosslink the polycarbonate-polyurethane composition and provide functional groups to react with the bioactive agent. However, present claim 26 only requires two molecules of crosslinking agent, one to react with the two (some) of the organic acid functional groups and another to be able to react with a bioactive agent molecule. Two molecules are clearly present in the 5% crosslinking agent example of Shults pointed out by the Applicant; see page 6, lines 9-10 of the August 13, 2007 response that cites column 14, lines 4-8 of Shults. Since a mole of material contains 6.023×10^{23} molecules, it is clear that even 6, 10, or 20 grams of carbodiimide would contain at least two molecules.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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